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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/976,987	10/12/2001	Raymond Clarke	10621-3	4161

7590 06/18/2002

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EXAMINER	
RHEE, JANE J	
ART UNIT	PAPER NUMBER
1772	4

DATE MAILED: 06/18/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

RO

Office Action Summary	Application No.	Applicant(s)	
	09/976,987	CLARKE ET AL.	
	Examiner	Art Unit	
	Jane J Rhee	1772	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8,11-16 and 20-29* is/are pending in the application.

4a) Of the above claim(s) *12,14 and 27* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8,11,13,15-16,20-26,28-29* is/are rejected.

7)☒ Claim(s) *5 and 22* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

This application contains claims directed to the following patentably distinct species of the claimed invention: coating polymer is: a) polydimethyl siloxane; b) cis-polybutadiene, poly(4-methylpentene) or ethylene-propylene rubber;c) an acrylate polymer containing at least 40% by weight of units derived from a cycloalkyl acrylate or methacrylate; a fluoropolymer; an acrylate polymer containing units derived from a fluoroalkyl acrylate or methacrylate; an acrylate polymer containing 10 to 70% of units derived from a polyethylene glycol acrylate or methacrylate.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, no claim is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

During a telephone conversation with Mr. Richardson on June 12, 2002 a provisional election was made with traverse to prosecute the invention of a) polydimethyl siloxane, claim 11 and 26. Affirmation of this election must be made by applicant in replying to this Office action. Claim 12, 14 and 27 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Specification

The amendment filed 10/12/00 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material

which is not supported by the original disclosure is as follows: a membrane wherein substantially 100% of the pores in the microporous film have a pore size of less than 0.24 micron.

Applicant is required to cancel the new matter in the reply to this Office Action.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

1. Claims 1-4,6-8,14-16 are rejected under the judicially created doctrine of double patenting over claims 1-16 of U. S. Patent No. 6376032 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: A gas permeable membrane which is useful in the packaging respiring biological materials and which comprises a microporous polymeric film comprising a network of interconnected pores such that gases can pass through the

film, and a coating on the microporous film wherein the polymeric coating has a thickness such that the membrane has a P_{10} ratio, over 10°C range between –5 and 15°C of at least 1.3; has a oxygen permeability (OTR), at all temperatures between 20°C and 25°C, of at least 775,000 ml/m^2.atm.24hrs (50,000cc/100 $inch^2$.atm.24hrs.) and has a CO_2/O_2 permeability ratio (R) of at least 1.5; the P_{10}, OTR, and R values being measured at a pressure of 0.035kg/cm^2 (0.5psi). A membrane wherein the microporous film comprises a polymeric matrix selected form the group consisting of an essentially linear ultrahigh molecular weight polyethylene having an intrinsic viscosity of at least 18 deciliters/g and an essentially linear ultrahigh molecular weight polypropylene having an intrinsic viscosity of at least 6 deciliters/g. A membrane wherein at least 70% of the pores in the microporous film have a pore size of less then 0.24 micron. A membrane wherein at least 90% of the pores in the microporous film have a pore size of less than 0.24 micron. A membrane wherein at least 80% of the pores in the microporous film have a pore size less than 0.15 micron and at least 70% of the pores have a pore size less than 0.11 micron. A membrane which as an OTR of at least 1,550,000 ml/m^2.atm.24hrs (100,000cc/$inch^2$.atm.24hrs), and an R ratio of at least 2, the OTR and R values being measured at a pressure of 0.7 kg/cm^2 (10psi). A membrane which has an OTR of at least 2,325,000 ml/m^2.atm.24hrs (150,000cc/100$inch^2$.atm.24hrs) at a pressure of 0.7 kg/cm^2 (10psi). A membrane wherein the microporous polymeric film contains pores which are partially blocked by a polymer having an R ratio of leas than 1.3 or by a particulate material, or (b) has an OTR before coating of less than 15,500,000 (1,000,000). A package which is stored in

air and which comprises a seal container, and within the sealed container, a respiring biological material and a packaging atmosphere around the biological material; the sealed container including one or more permeable control sections which provide at least the principal pathway for oxygen and carbon dioxide to enter or leave the packaging atmosphere, at least one of the permeable control section being gas permeable membrane.

Furthermore, there is no apparent reason why applicant was prevented from presenting claims corresponding to those of the instant application during prosecution of the application which matured into a patent. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

It is the examiner's position that the gas permeable membrane of US patent 6,376,032 is identical to or only slightly different than the gas permeable membrane prepared by the method of the claim(s), because both gas permeable membrane has a microporous polymeric film and a polymeric coating on the microporous film, both has an oxygen permeance of at least 775,000 ml/m^2.atm.24hrs (50,000cc/100 $inch^2$.atm.24hrs.and has a CO_2/O_2 permeability ratio (R) of at least 1.5. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985). The burden has been shifted to the applicant to show

obvious difference between the claimed product and the prior art product. *In re Marosi*, 218 USPQ 289 (Fed. Cir. 1983). The US patent 6376032 either anticipated or strongly suggested the claimed subject matter. It is noted that if the applicant intends to rely on Examples in the specification or in a submitted declaration to show non-obviousness, the applicant should clearly state how the Examples of the present invention are commensurate in scope with the claims and how the Comparative Examples are commensurate in scope with the US Patent 6376032.

2. Claims 20-21,23-25,29 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-16 of U.S. Patent No. 6376032. Although the conflicting claims are not identical, they are not patentably distinct from each other because it would have been obvious to one of ordinary skill in the art to have provided the recited pore size and density in the microporous film in the following limitations wherein less than 20% of the pores in the microporous film have a pore size less than 0.014 micron and less than 20% of the pores in the microporous film have a pore size greater than 0.13 micron since Patent No. 6376032 teaches the recited permeability and CO_2/O_2 permeance ratio for use in preserving produce.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1,2,7,8, 11, 13, 15-16 are rejected under 35 U.S.C. 102(b) as being unpatentable by Antoon Jr.(5160768).

Antoon Jr. discloses a gas permeable membrane that comprises a microporous polymeric film comprising a network of interconnected pores such that gases can pass through the film and a polymeric coating on the microporous film (col. 2 lines 43-50). Antoon Jr. discloses that the polymeric coating membrane has a oxygen permeability (OTR), of at least 775,000 ml/m^2.atm.24hrs (50,000cc/100 $inch^2$.atm.24hrs.) (col. 2 line 52) and has a CO_2/O_2 permeability ratio (R) of at least 1.5 (col. 2 line 54). Antoon Jr. discloses that the microporous membrane can be made of polyethylene or polypropylene (col. 3 lines 54-56). Antoon Jr. discloses a membrane which as an OTR of at least 1,550,000 ml/m^2.atm.24hrs (100,000cc/$inch^2$.atm.24hrs) (col. 2 line 52), and an R ratio of at least 2 (col. 2 line 54). Antoon Jr. discloses a membrane, which has an OTR of at least 2,325,000 ml/m^2.atm.24hrs (150,000cc/100$inch^2$.atm.24hrs) (col. 2 line 52). Antoon Jr. discloses wherein the coating polymer is polydimethyl siloxane (col. 3 lines 35-42). Antoon Jr. discloses that the coating polymer is crosslinked (col. 3 lines 35-42). Antoon Jr. discloses a package which is stored in air and which comprises a seal container, and within the sealed container, a respiring biological material and a packaging atmosphere around the biological material; the sealed container including one or more permeable control sections which provide at least the principal pathway for oxygen and carbon dioxide to enter or leave the packaging atmosphere, at least one of the permeable control section

being gas permeable membrane (col. 5 lines 34-35 and col. 6 lines 1-15). Since Antoon, Jr. teaches that which appears to be identical to that disclosed by the applicant with respect to permeability, the recited properties not specifically disclosed by Antoon, Jr. would be inherent.

It is the examiner's position that the gas permeable membrane of US patent 5160768 is identical to or only slightly different than the gas permeable membrane prepared by the method of the claim(s), because both gas permeable membrane has a microporous polymeric film and a polymeric coating on the microporous film, both has an oxygen permeance of at least 775,000 ml/m^2.atm.24hrs (50,000cc/100 $inch^2$.atm.24hrs.and has a CO_2/O_2 permeability ratio (R) of at least 1.5. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985). The burden has been shifted to the applicant to show obvious difference between the claimed product and the prior art product. *In re Marosi*, 218 USPQ 289 (Fed. Cir. 1983). The US patent 6376032 either anticipated or strongly suggested the claimed subject matter. It is noted that if the applicant intends to rely on Examples in the specification or in a submitted declaration to show non-obviousness, the applicant should clearly state how the Examples of the present invention are

commensurate in scope with the claims and how the Comparative Examples are commensurate in scope with the US Patent 5160768.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 2-6,20-26,28 rejected under 35 U.S.C. 103(a) as being unpatentable over Antoon Jr. (5160768).

Antoon Jr. discloses a gas permeable membrane that comprises a microporous polymeric film comprising a network of interconnected pores such that gases can pass through the film and a polymeric coating on the microporous film (col. 2 lines 43-50). Antoon Jr. discloses that the polymeric coating membrane has a oxygen permeability (OTR), of at least 775,000 ml/m^2.atm.24hrs (50,000cc/100 $inch^2$.atm.24hrs.) (col. 2 line 52) and has a CO_2/O_2 permeability ratio (R) of at least 1.5 (col. 2 line 54). Antoon Jr. discloses that the microporous membrane can be made of polyethylene or polypropylene (col. 3 lines 54-56). Antoon Jr. discloses a membrane which as an OTR of at least 1,550,000 ml/m^2.atm.24hrs (100,000cc/$inch^2$.atm.24hrs) (col. 2 line 52), and an R ratio of at least 2 (col. 2 line 54). Antoon Jr. discloses a membrane, which has an OTR of at least 2,325,000 ml/m^2.atm.24hrs

(150,000cc/100inch^2.atm.24hrs) (col. 2 line 52). Antoon Jr. discloses wherein the coating polymer is polydimethyl siloxane (col. 3 lines 35-42). Antoon Jr. discloses that the coating polymer is crosslinked (col. 3 lines 35-42). Antoon Jr. discloses that the microporous polyethylene or polypropylene (col. 3 lines 54-65). Antoon Jr. discloses a package which is stored in air and which comprises a seal container, and within the sealed container, a respiring biological material and a packaging atmosphere around the biological material; the sealed container including one or more permeable control sections which provide at least the principal pathway for oxygen and carbon dioxide to enter or leave the packaging atmosphere, at least one of the permeable control section being gas permeable membrane (col. 5 lines 34-35 and col. 6 lines 1-15)

Antoon Jr. fail to teach a membrane wherein the microporous film comprises a polymeric matrix selected form the group consisting of an essentially linear ultrahigh molecular weight polyethylene having an intrinsic viscosity of at least 18 deciliters/g and an essentially linear ultrahigh molecular weight polypropylene having an intrinsic viscosity of at least 6 deciliters/g. Antoon Jr. fails to teach the recited average pore size and densities of the pores. Since Antoon Jr. teaches a microporous membrane having the recited permeability and CO_2/O_2 permeance ratio for use in preserving produce, as disclosed by the applicant, it would have been obvious to one of ordinary skill in the art to have provided the recited pore size and density in the microporous film. The use of the well known ultra high molecular weight polyethylene and propylene would have been obvious to one having ordinary skill in the art in view of the teaching of the microporous polyolefin membrane to have produced increased strength to the laminate

material. Since Antoon, Jr. teaches that which appears to be identical to that disclosed by the applicant with respect to permeability, the recited properties not specifically disclosed by Antoon, Jr. would be inherent.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jane J Rhee whose telephone number is 703-605-4959. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Harold Pyon can be reached on 703-308-4251. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-5408 for regular communications and 703-301-9999 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

Jane Rhee
June 12, 2002

HAROLD PYON
SUPERVISORY PATENT EXAMINER
1772

6/14/02